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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,052	03/24/2004	Richard S. Blumberg	18989-033	4208

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ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER

KOSAR, ANDREW D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/808,052

Applicant(s)

BLUMBERG, RICHARD S.

Examiner

Andrew D. Kosar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-50 are pending and require restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 9, drawn to a method of inhibiting CD1-mediated antigen presentation with a MTP inhibitor, classified in class 514, subclass 2.
- II. Claims 10-12, drawn to a method of inhibiting a symptom of a CD1-mediated immunopathology with a MTP inhibitor, classified in class 514, subclass 2.
- III. Claim 13, drawn to a method of inhibiting an association of MTP and CD1 with an MTP-binding compound, classified in class 514, subclass 2.
- IV. Claim 14, drawn to a method of inhibiting association of MTP and CD1 with an MTP-binding compound and a CD1-binding compound, classified in class 514, subclass 2.
- V. Claim 15, drawn to a method for reducing lipidation of CD1d in a cell with an inhibitor of CD1d α_1 , α_2 , or α_3 binding with MTP classified in class 514, subclass 2.
- VI. Claims 21-23, 35-37, and 44-46, drawn to a method of inhibiting inflammation with an heterocyclic MTP inhibitor, classified in class 514, subclass 183.
- VII. Claims 24, 25, 38, 39, 47, and 48, drawn to a method of inhibiting inflammation with a nucleic acid MTP inhibitor, classified in class 514, subclass 44.

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VIII. Claims 27-29, drawn to a method for preventing or alleviating a symptom of an inflammatory disorder with a heterocyclic MTP inhibitor, classified in class 514, subclass 183.

IX. Claims 30 and 31, drawn to a method for preventing or alleviating a symptom of an inflammatory disorder with a nucleic acid, classified in class 514, subclass 44.

Claims 1-8, 16-20, 24, 25, 34, 40-43, 49, and 50 link(s) inventions VI and VII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-8, 16-20, 24, 25, 34, 40-43, 49, and 50.

Claims 26, 32, and 33 link(s) inventions VIII and IX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 26, 32, and 33.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods with different effects/outcomes and are not disclosed as capable of use together. One would not necessarily have to practice one method in the practice of

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another. For example, one would not be practicing the method of administration of a CD1-inhibitory nucleic acid in a T-cell inhibitory dose to practice the method of inhibiting CD1-mediated antigen presentation with a non-nucleic acid composition. Additionally, one would not have to inhibit a symptom of a CD1 mediated immunopathology in order to practice the method of reducing lipidation of CD1d in a cell. It is noted from the specification that the methods are practiced *in vivo*, *in vitro*, or *ex vivo*, and *in vivo*, and the methods would be practiced on distinct patient populations with distinct etiologies, with distinctly different desired effects.

Additionally, the method of invention V requires two compounds, not required by any other group, and some methods merely require a binding compound, not an inhibitor. Furthermore one would not necessarily have to practice any of the other methods in order to prevent a symptom of an inflammatory disorder.

This application contains claims directed to the following patentably distinct species of the claimed invention:

MTP inhibitors of generic formula (I) in claims 21-23, 27-29, 35-37, and 44-46.

SEQ ID NO:1 and 2 in claims 24, 25, 30, 31, 38, 39, 47, and 48.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, commensurate with the elected invention, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Claims 1-20, 24-26, 32-34, 40-43, 49, and 50 are generic with respect to 'MTP inhibitor'.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

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thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The search for each of the above inventions is not co-extensive, particularly with regard to the non-patented literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. For example, the search for the method of preventing a symptom of a inflammatory disorder with an MTP inhibitor would not necessarily lead to the discovery of all pertinent literature regarding the method of reducing lipidation of a CD1d cell. Because these inventions are distinct for the reasons given above, and the search for one invention would not necessarily lead to the discovery

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of another invention, restriction for examination purposes as indicated is proper, and to not restrict would be an undue burden on the Examiner.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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